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08/650783

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/650,783	05/20/96	SCHMITT	P 498-53-CON
		33M1/1105	EXAMINER
			CUDDIHY, F
		ART UNIT	PAPER NUMBER
		3308	5
		DATE MAILED:	11/05/96

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on MAY 20, 1996

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-17 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

*Drawings*

1. The drawings are objected to because Figure 1 is not designated by a legend such as "Prior Art". The legend is necessary in order to clarify what applicant's invention is. MPEP 608.02(g). Correction is required.

**35 U.S.C. 112**

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description of the invention.

Applicant fails to adequately define what is meant by "peak to peak amplitude."

Throughout the specification, applicant points out the criticality of peak-to-peak amplitude. However, there appears to be a discrepancy as to what the maximum peak-to-peak amplitude must actually be. On page 3, lines 30-31, applicant recites a peak-to-peak amplitude not in excess of 0.5 mm, while on page 7, lines 22-24, applicant discloses a peak-to-peak amplitude of no greater than 0.6 mm. This discrepancy is a source of confusion

insofar as the criticality of peak-to-peak amplitude is concerned.

4. Claims 4, 7, 8, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification.

5. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1 and 5, it is not entirely clear what "fabric thickness" refers to. Clarification is requested.

With respect to claims 6, 11 and 12, it is not entirely clear what "wall thickness" refers to. Clarification is requested.

Claim 11, lines 6-12, includes a double recitation of elements; that is, "a plurality of wave-like crimps".

Claim 13, lines 1-3, is rejected as being of improper dependent form for failing to further limit the subject matter of a previous claim. That is, claim 13, like claim 11, recites "... a crimp ... of no less than 8 crimps per centimeter".

With respect to claims 11 and 16, the recitation of "may be" is indefinite for failing to positively claim the limitation.

The claims will be treated as best as they can given applicant's failure to adequately define what is meant by "peak to peak amplitude."

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --  
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 11 and 16 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lunn (5,476,506).

With respect to claim 11, Lunn discloses a woven tubular vascular graft, the body of the prosthesis having a plurality of longitudinally spaced wave-like generally uniform crimps along the length, and on both sides, thereof (column 3, line 3 - column 4, line 67; column 5, line 59 - column 6, line 67; figures 1-3).

With respect to claim 16, the device disclosed by Lunn is certainly capable of being compressed for insertion into an endoluminal catheter.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the

time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

9. Claims 1, 4-7 and 12-14 are rejected under 35 U.S.C. § 103 as being obvious over Lunn (5,476,506) in view of DT 2913510.

With respect to claims 1, 4-7 and 12-14, Lunn discloses a woven tubular vascular graft, the body of the prosthesis having a plurality of longitudinally spaced wave-like generally uniform crimps along the length, and on both sides, thereof (column 3, line 3 - column 4, line 67; column 5, line 59 - column 6, line 67; figures 1-3). However, the device of Lunn, while disclosing applicants' crimp frequency, does not disclose applicants' particular claimed wall thickness.

DT 2913510 teaches a prosthetic blood vessel having corrugated walls of from 0.02 to 0.04 millimeters in thickness (see abstract).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the device of Lunn with a material having such a wall thickness as taught by DT 2913510 in order to provide for a crimped graft having enhanced resistance to collapse by kinking.

10. Claim 10 is rejected under 35 U.S.C. § 103 as being obvious over Lunn (5,476,506) in view of DT 2913510 further in view of De Goicoechea et al (5,383,927).

With respect to claim 10, the device set forth in paragraph 9 supra discloses the invention substantially as claimed. However, the device set forth in paragraph 9 supra does not disclose a bifurcated tubular graft body.

While a bifurcated tubular graft body would have been within the purview of the artisan in possession of ordinary skill, De Goicoechea is set forth as an example of a bifurcated vascular prosthesis having crimps along its length, thereby further serving to strengthen its walls (column 7, lines 18-40).

Accordingly, it would have been obvious to one having ordinary skill in the art to have provided the device disclosed in paragraph 9 supra in bifurcated form in order to provide for a vascular prosthesis enjoying enhanced strength and utility in a diseased bifurcated blood vessel.

11. Claim 17 is rejected under 35 U.S.C. § 103 as being obvious over Lunn (5,476,506) in view of De Goicoechea et al (5,383,927).

With respect to claim 17, Lunn discloses the invention substantially as claimed (see paragraph 7 supra). However, Lunn does not disclose a bifurcated tubular graft body.

While a bifurcated tubular graft body would have been within the purview of the artisan in possession of ordinary skill, De Goicoechea is set forth as an example of a bifurcated vascular

prosthesis having crimps along its length, thereby further serving to strengthen its walls (column 7, lines 18-40).

Accordingly, it would have been obvious to one having ordinary skill in the art to have provided the device disclosed in paragraph 7 supra in bifurcated form in order to provide for a vascular prosthesis enjoying enhanced strength and utility in a diseased bifurcated blood vessel.

12. Claims 2-3 and 15 are rejected under 35 U.S.C. §103 as being obvious over Lunn (5,476,506) in view of DT 2913510 further in view of Arpesani (WO 88/06026).

With respect to claim 2-3 and 15, the device set forth in paragraph 9 supra discloses the invention substantially as claimed. However, the device set forth in paragraph 9 supra does not disclose a tubular graft body having an x-ray detectable radiopaque yarn incorporated therein.

Arpesani teaches a tubular prosthesis having a radiopaque portion defined by a longitudinal filiform element serving to aid in proper positioning of the prosthesis (figures 1 and 2, element 5a).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have incorporated just such a radiopaque longitudinal filiform element, as taught by Arpesani, in the device set forth in paragraph 9 supra in order to ensure the proper positioning of the graft device within the body.

*Conclusion*

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hood (4,545,082) and Hood (WO 8303347) disclose corrugated vascular prostheses.

Jones (4,202,349) discloses radiopaque vessel markers.

14. Any questions concerning this communication should be directed to Francis K. Cuddihy at telephone number (703)-308-2996. In the event that Applicant/Representative is unable to reach Mr. Cuddihy directly or by voice mail, Applicant may contact Supervisory Patent Examiner Mr. John Weiss at telephone number (703)-308-2702.

For those questions of a general nature, the Group 3300 Receptionist may be reached at telephone number (703)-308-0858.

Additionally, formal facsimile communications should be directed to the Group 3300 Main Fax number (703)-305-3590; informal facsimile communications should be directed to the Art Unit 3308 Fax number (703)-308-0131. Kindly place my name, art unit, and application serial number on the facsimile cover sheet.

Francis K. Cuddihy *FKC*  
Assistant Examiner  
October 29, 1996

  
JOHN G. WEISS  
SUPERVISORY PATENT EXAMINER  
GROUP 3300